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| * 1. Is the research or demonstration project conducted or supported by a federal department or agency and designed to study, evaluate, improve, or otherwise examine public benefit or service programs? [[1]](#endnote-1) | |
| Yes | Continue |
| No | This research is not exempt under this category. |
| * 1. Does the federal department or agency conducting or supporting the research have a publicly accessible web site or other manner for publishing a list of the research and demonstration projects that are conducted or supported under this provision? | |
| Yes | Your research may be exempt under this category. To be exempt, the research or demonstration project must be published on this list prior to commencing the research involving human subjects. |
| No | This research is not exempt under this category. |
| * If you answered ‘yes’ to all of the questions above, your project likely qualifies for exemption:   + Complete any additional category worksheets applicable to your research;   + Proceed with completing Parts III-VI of the Exempt Application Form;   + Submit the items noted in the Submission Checklist at the end of the form to Research Compliance Services (RCS). RCS will review and verify the exempt determination;   + If RCS determines the study does not qualify for exemption, you will need to prepare and submit a protocol using the Initial Review Application. * If you answered ‘no’ to any of the questions above, this research is not exempt under this category. Return to the screening form to identify alternative categories for exemption. If you conclude that no categories are applicable to your research, your study is not eligible for exemption. Proceed with preparing an Initial Review Application. | |

1. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

   Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects. [↑](#endnote-ref-1)